PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference FP157-C4319	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2005/006019	30.03.2005	31.03.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant
MORINAGA MILK INDUSTRY CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/006019

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 14-16

because:

☒ the said international application, or the said claims Nos. 14-16
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of claims 14-16 concern a method for treating the human body by therapy. (PCT Article 34 (4) (a) (i), PCT Rule 67.1 (iv))

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14-16

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1, 9, 10	YES
	Claims	2-8, 11-13	NO
Inventive step (IS)	Claims	1	YES
	Claims	2-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations:

This opinion is presented based on the following documents cited in the international search report.

Document 1: YEH, G. Y., et al., Diabetes Care, 2003, 26(4), p. 1277-1294
Document 2: JP 2003-286185 A (Deiri Fuzu Kabushiki Kaisha)
Document 3: ABOU-ZEID, A. H. S., Egypt. J. Pharm. Sci., 1998, 39(4-6), p. 379-398
Document 4: JP 9-70278 A (Kowa Kagaku Kogyo Kabushiki Kaisha)
Document 5: WO 03/059360 A1 (MEDICAL ISOTOPES, INC.)

oClaim 1

Document 3 describes various triterpene derivatives having a hypoglycemic effect. When we compare the invention of claim 1 with the invention described in claim 3, they differ because in the former a glucopyranoside group is substituted at the 3 position of a steroid scaffold, but in the latter there is no statement concerning such a substituent group. Moreover, in the former the rings are not condensed on the steroid scaffold, but in the latter they are condensed.

On the other hand, document 4 describes a compound that exhibits a glucose-suppressing effect, and a ring is substituted at the 3 position of the steroid scaffold, but that structure is different from the compound of claim 1. In addition, although document 5 describes a compound wherein a glucopyranoside group is substituted at the 3 position of a steroid scaffold, the action thereof is to inhibit cholesterol absorption, and that differs from the effect of correcting hyperglycemia. This being the case, this authority finds that based on the descriptions in documents 3-5, persons skilled in the art could not easily conceive of the invention of claim 1.

Therefore, the invention of claim 1 involves an inventive step also based on the inventions described in documents 3-5.

(Continued in supplemental box)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V.

oClaims 2-8 and 11-13

Document 1 (Table 1; page 1287, left column) states that an extract of *Aloe vera* exhibits a hypoglycemic action. In addition, document 2 states that a squeezed liquid of *Aloe vera* exhibits a hypoglycemic action and can be used in beverages and cosmetic products. When we compare the inventions of claims 2-8 and 11-13 with the inventions described in documents 1 and 2, the former appear to differ from the latter because they contain a compound having a specific chemical structure.

However, both are identical with respect to the fact that an extract or fraction of *Aloe vera* is used as the active ingredient, and because this authority finds that there is no information presented that the two contain a completely different ingredient, no clear difference can be found between the inventions of claims 2-8 and 11-13 and the inventions described in documents 1 and 2.

Therefore, based on the descriptions in documents 1 and 2, the inventions of claims 2-8 and 11-13 lack novelty and an inventive step.

oClaims 9 and 10

The inventions of claims 9 and 10 differ from the inventions described in documents 1 and 2 with respect to the specific extraction process.

However, when extracting ingredients from plants, it is conventional practice of persons skilled in the art to use an organic solvent and hot water, and therefore this authority finds that using such means to extract the ingredients described in documents 1 and 2 presents no particular technical difficulty to persons skilled in the art.

Therefore, based on the descriptions in documents 1 and 2, the inventions of claims 9 and 10 lack an inventive step.